

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P210903PCT	FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/NL2005/000038	International filing date (day/month/year) 19.01.2005	Priority date (day/month/year) 19.01.2004
International Patent Classification (IPC) or national classification and IPC INV. A61L27/32 A61L31/08		
Applicant UMC ST. RADBOUD		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in Item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 14.11.2005	Date of completion of this report 20.04.2006	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Menidjel, R Telephone No. +31 70 340-3680 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/NL2005/000038

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-20 as originally filed

Claims, Numbers

1-12 as originally filed

Drawings, Sheets

1/5-5/5 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/NL2005/000038

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-12
	No: Claims	
Inventive step (IS)	Yes: Claims	1-12
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 94/22513 A (US HEALTH ; ZABETAKIS PAUL MICHAEL (US)) 13 October 1994 (1994-10-13)

D2: ANTONOV E N ET AL: "Laser modification of biocompatible calcium phosphate coatings" LASERS IN THE LIFE SCIENCES, vol. 9, no. 3, 2000, pages 127-142, XP008031820 UNITED KINGDOM ISSN: 0886-0467

1. Novelty (Article 33(2) PCT)

- The subject-matter of present claims 1-12 is considered as novel over the cited prior art for the following reasons (Article 33(2) PCT):

- Document D1 describes flexible medical devices such as catheters that are provided with a bioactive coating of a crystalline calcium phosphate compound on substrates such as silicone, polyurethane and polyvinyl chloride. One method described consists in coating the device by pulsed laser deposition with an amorphous coating of hydroxyapatite and subsequently performing laser annealing to crystallize the coating. Post-deposition annealing is described as most suitable for crystallising calcium phosphate coatings on temperature sensitive substrates. The laser annealing is performed with lasers such as ArF (193 nm), KrF (248 nm), XeF or XeCl (above 300 nm). The energy density ranges from 1-500 mJ/cm² with a preferred range lying between 100-200 mJ/cm² and 248 nm.

Document D1 differs from the claimed subject-matter in that **the laser light is <200 nm**.

- Document D2 relates to crystalline hydroxyapatite coatings on implants made of a metallic substrate or Teflon by IR and UV (213 nm; 248 nm) pulse laser irradiation. In document D2 the laser annealing is said to increase crystallinity and provide an improved response to human osteoblasts.

Document D2 differs from the claimed subject-matter in that **it does refer to a laser light of <200 nm and 10-1000 mJ/cm²**.

2. Inventive step (Article 33(1),(3) PCT)

- The subject-matter of present claims 1-12 is considered as being inventive for the following reasons (Article 33(1),(3) PCT):
- The problem to be solved by the present application is to provide a method for providing a crystalline calcium phosphate (CaP) coating on a temperature-sensitive polymeric substrate.
- The solution proposed in the present application is a method for providing a polymeric implant object with a crystalline calcium phosphate (CaP) coating, said method comprising the step of irradiating a polymeric substrate having deposited thereon an amorphous CaP coating with laser light of $<200\text{ nm}$ and $10\text{-}1000\text{ mJ/cm}^2$ (see claim 1).
- Document D1, which is considered as the closest prior art, describes flexible medical devices such as catheters that are provided with a bioactive coating of a crystalline calcium phosphate compound on substrates such as silicone, polyurethane and polyvinyl chloride (polymeric substrates). One method described consists in coating the device by pulsed laser deposition with an amorphous coating of hydroxyapatite and subsequently performing laser annealing to crystallize the coating.
- The difference between the teaching of the closest prior art and the claimed subject-matter is that the claimed method implies a laser light of $<200\text{ nm}$ and $10\text{-}1000\text{ mJ/cm}^2$.
- The technical effect of this difference is that CaP coatings can only be effectively crystallized on temperature-sensitive substrates, while being laser annealed from the surface.
- Starting from D1, the skilled person had no incentive to come to the claimed solution, and therefore, the subject-matter of present claims 1-12 is considered as being inventive according to Article 33(1),(3) PCT.

3. Industrial Application (Article 33(4) PCT)

- The subject-matter of present claims 1-12 is considered to be industrially applicable; claims 1-12 therefore, satisfy the criterion set forth in Article 33(4) PCT.